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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,053	09/28/2000	James Oliver Dolly	17044DIV1 (AP)	2480

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Carlos A Fisher
Allergan Ing
T2-7H
2525 Dupont Drive
Irvine, CA 92612

EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/676,053	DOLLY ET AL	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31,32 and 34-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31,32 and 34-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed on 10-16-2006 are acknowledged. Claims 31-32 and 35 have been amended. Claims 37-45 have been added. Claims 31-32 and 34-45 are pending and currently under examination.

Objections Maintained

Oath/Declaration

The objection to the oath or declaration as being defective is maintained. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Claim Rejections Withdrawn

The rejection of claim 32 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "active Clostridial neurotoxin" is withdrawn in light of the amendment thereto.

The rejection of claims 31 and 34-36 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 6 and 8-9 of U.S. Patent No. 6,203,794 is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The instant claims are drawn to a composition comprising **any** active Clostridial neurotoxin.(claim 31) joined to a drug wherein the drug can be an intracellular acting drug generally (claim 34) or a protein synthesis toxin, an inhibitor of neurotransmitter release, a neuronal calcium channel blocker, a ribozyme or an oligonucleotide specifically (claims 34 and 36). Moreover, the specific toxin can be tetanus toxin, botulinum toxin A, botulinum toxin B, botulinum toxin C, botulinum toxin D, botulinum toxin E, botulinum toxin F or botulinum toxin G (claim 35).

Claims 31-32 and 34-45 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bizzini (U.S. Patent 4,594,336 -- IDS) for the reasons set forth in the previous Office action in the rejection of claims 31-32 and 34-36.

Applicant argues:

1. The toxins disclosed by Bizzini are not active.

2. Since the compositions of Bizzini lack a functional light chain they cannot anticipate the compositions of the instant claims.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, as acknowledged by Applicant on page 8 of his response, the toxin disclosed by Bizzini has a proteolytic activity 1000-fold less than that of the full-length

toxin. As the instant claims only require the composition have "some" enzymatic activity, the compositions of Bizzini meet the limitation.

In response to applicant's argument that the references fail to show certain features of applicant's invention (Point 2), it is noted that the features upon which applicant relies (i.e., the toxin have a functional light chain) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

As outlined previously, Bizzini teaches a composition comprising a tetanus toxin bound to a thiol group and that said composition could be used to transport agents (medicines) to the central nervous system (see column 2, lines 56-60). Moreover, Bizzini teaches that the toxin can be any protein toxin (see page 4) and that said medicines could be transported into the nervous system via said medicine being bound to the thioliated tetanus toxin (see column 6, lines 1-40). Consequently, Bizzini anticipates the limitations of claims 31-32 and 35. Bizzini differs from the instant claims in that he does not explicitly disclose the "medicines" recited in claims 34 and 36. However, since Bizzini discloses "Medicine is intended to designate according to the invention any substance having pharmacological properties, such as pharmacological agents, chemotherapeutic agents and the like". Consequently, the specific limitations recited in claims 34 and 36 constitute obvious variations of the compositions disclosed by Bizzini. Moreover, since Bizzini et al. does not explicitly disclose the toxin used in "inactive", it is deemed, in absence of evidence to the contrary, to be active.

Claims 31-32, 35-41 and 44-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Arnon (U.S. Patent 5,562,907 -- IDS) for the reasons set forth in the previous Office action in the rejection of claims 31-32 and 36.

Applicant argues:

1. The present claims recite in part "a Clostridial neurotoxin heavy chain which has binding specificity for a target nerve cell".

2. The instant claims do not recite an a carrier component.

Applicant's arguments have been fully considered and deemed non-persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a Clostridial neurotoxin heavy chain which has binding specificity for a target nerve cell) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With regard to Point 2, said claims recite the term "comprising". Consequently, the presence of non-recited components is not precluded.

As the compositions disclosed by Arnon comprises the necessary components i.e. an active neurotoxin and a "drug" (i.e. antibody etc). The limitations of the instant claims are met.

As outlined previously, Arnon discloses "recombinant toxins" comprising a botulinum neurotoxins and antibodies (see column 13, lines 1-25) or optionally cation-channel blocking agents (see column 14, lines 57-67). It should be noted that the antibodies are deemed to be "drugs" since they are used to prevent unwanted side-effects to the neurotoxin (see column 13,

lines 35-55). Moreover, since Arnon does not explicitly disclose the toxin used in "inactive", it is deemed, in absence of evidence to the contrary, to be active.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Mon - Fri 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272 0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ROBERT A. ZEMAN
PRIMARY EXAMINER
December 25, 2006